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IN DEFENSE OF SCIENTIFIC INTEGRITY: EXAMINING THE IARC MONOGRAPH PROGRAMME AND GLYPHOSATE REVIEW

Tuesday, February 6, 2018

House of Representatives,

Committee on Science, Space, and Technology,

Washington, D.C.

Committee Hearings

of the

U.S. HOUSE OF REPRESENTATIVES

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The Committee met, pursuant to call, at 10:06 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Lamar Smith [Chairman of the Committee] presiding.

Chairman SMITH. The Committee on Science, Space, and Technology will come to order. Without objection, the Chair is authorized to declare recesses of the Committee at any time.

Welcome to today's hearing entitled ''In Defense of Scientific Integrity: Examining the IARC Monograph Programme and Glyphosate Review.''

I recognize myself for 5 minutes for an opening statement, and then I'll recognize the opening--I mean the Ranking Member as well.

Today, we will examine the U.S. taxpayer-funded IARC Monograph Programme and its assessment of the herbicide glyphosate, more commonly known as Roundup. We must ensure that the underlying science behind assessments that influence policy and the public is based on sound science. The American people deserve to know the truth about which substances are safe and which ones pose a risk. Glyphosate is the most widely used herbicide in the world. Americans and people across the globe rely on these crops for high quality, affordable food.

There are real repercussions to IARC's unsubstantiated claims, which are not backed by reliable data. Labeling requirements will drive costs up for farmers and consumers and create unjustified public fear. IARC's irresponsible handling of data does real harm to job creators and the

public's view of the scientific process.

Agencies such as IARC have a responsibility to adhere to the scientific method and evaluate all relevant scientific studies, weigh the evidence, and come to a conclusion that can be reproduced. Following the scientific method also means forming a conclusion only after all data has been considered.

According to information gathered by the Committee, there appear to be serious problems with the science underlying IARC's assessment of glyphosate. The news media recently revealed evidence of data deletion and manipulation of draft assessments before final publication. IARC's conclusion about glyphosate relied only on data that was favorable to its conclusion and ignored contradictory data.

In its assessment, IARC did no direct evaluation of glyphosate's effect on humans, no evaluation whatsoever. Specifically, IARC appears to have intentionally omitted data that showed glyphosate does not cause cancer. It's no surprise that the Monograph Programme has refused to publish any of its draft assessments. If there is nothing to hide, why the secrecy?

The manipulation of scientific data and lack of transparency is not the only defect in IARC's glyphosate assessment. Besides altering the data used in the assessment, the Monograph Working Group failed to consider

the most significant study on human exposure to glyphosate. The Agricultural Health Study, which was a result of a collaboration of several federal agencies such as the National Cancer Institute, National Institute of Environmental Health Sciences, and the Environmental Protection Agency presented information they had collected on over 50,000 humans. Aaron Blair, the Chair of the Monograph Programme at the time, admitted in a deposition that the study would, quote, ''altered IARC's analysis,'' end quote. However, this study was not considered by IARC.

In 2015, IARC published its findings on glyphosate, categorizing the herbicide as ''probably'' causing cancer. It has become apparent that the Monograph on glyphosate uses nothing more than cherry-picked science created by those who have a financial stake in the resulting conclusions.

The Monograph Programme is alone in its determination that glyphosate poses a cancer threat. Both the EPA and EFSA, a European regulatory agency, have reviewed glyphosate and determined that the chemical is unlikely to cause cancer. Last December, the EPA released a draft Human Health Risk Assessment evaluating the potential of glyphosate to cause cancer. The EPA body of research was then evaluated by a Scientific Advisory Panel composed of experts appointed during the Obama Administration. The EPA's draft assessment reviewed IARC's glyphosate Monograph and came to the

conclusion that glyphosate is unlikely to cause cancer.

The Committee has written several letters expressing concerns about the lack of sound science and biases found in IARC's program. When asked to provide a witness for this hearing, IARC Director Wild refused to attend. No doubt he could not defend IARC's glyphosate findings. The selective use of data and the lack of public disclosure raise questions about why IARC should receive any government funding in the future.

[The statement of Chairman Smith follows:]

********** INSERT 1 **********

Chairman SMITH. That concludes my opening statement, and the Ranking Member, the gentlewoman from Texas, is recognize for hers.

Ms. JOHNSON. Thank you very much, Mr. Chairman.

Chemicals have the potential to greatly improve our quality of life when developed and produced in a responsible manner. However, when produced or proliferated irresponsibly or without sufficient understanding of their potential impacts, chemicals can pose a grave and significant risk to every one of us.

Unfortunately, by the time we realize the harm being caused by unsafe exposure to such toxic chemicals, the damage has often already been done, and we're left regretting the fact that there might have been preventative actions we could have taken to protect ourselves if we had a better understanding of the hazards. If we knew then what we know now, would we have filled our homes, schools, businesses, hospitals with asbestos? Would we have supported the widespread installation of lead pipes to provide us with our daily drinking water? Most Americans who have had to suffer or who have seen their children and other loved ones suffer through the adverse health effects of exposures to dangerous chemicals would likely say no, of course not.

The chemicals we are discussing today--glyphosate--is also already one of the most widely used chemicals in

agriculture. For example, it is the key ingredient in Monsanto's herbicide Roundup that has helped farmers get greater yield of corn and other agriculture products. However, the widespread prevalence of glyphosate has raised serious concerns about its toxicity and potential cancer-causing properties.

That is why the work done by independent chemical assessment organizations like the World Health Organization and its International Agency for Research on Cancer is so critical to protecting the public health of--those organizations evaluate without prejudice or concern about profits, the health habits--hazards and risks posed by exposure to toxic chemicals. By contrast, there's been extensive documentation of efforts by the chemical industry to bias the science and public perception of their chemicals to protect their financial interests rather than the public health. If we are truly interested in defending scientific integrity, we should be doing more than simply hearing from the industry-friendly scientists.

As my colleagues may be aware, the EPA's Office of Inspector General has been investigating allegations that Monsanto attempted to influence officials at the Environmental Protection Agency who were central to EPA's own review of glyphosate, as well as potential collusion by those officials with Monsanto. If this committee really wishes to

do oversight in defense of scientific integrity, those allegations would certainly seem to be worthy of our attention. However, I am not holding my breath that the majority will undertake such an investigation.

Mr. Chairman, chemical companies will continue to innovate and manufacture chemicals that seek to improve human life, and I support their initiatives in doing so. But such innovations should not come at the cost of human health. That is why the work of independent organizations like IARC is so important and why we in Congress should be supporting that work rather than attempting to undercut it.

The minority staff has produced a staff report that documents some of the tactics Monsanto has used to undermine this IARC Monograph and scientific findings and glyphosate in general, and I'm attaching this report to my statement.

I thank you, Mr. Chairman, and I yield back.

[The statement of Ms. Johnson follows:]

********** INSERTS 2, 3 **********

Chairman SMITH. Okay. Thank you, Ms. Johnson.

Mr. WEBER. Mr. Chairman?

Chairman SMITH. Yes, the gentleman from Texas, Mr. Weber.

Mr. WEBER. If I may, I have reservations about entering this report into the record. This committee received the minority's report--staff report late last night and has not had sufficient time to completely review this report for factual accuracy. I am aware at this time--

Ms. JOHNSON. I didn't--oh, sorry.

Mr. WEBER. --of at least one statement of questionable accuracy. It's on page 15 and 16. The minority's report appears to suggest that the current EPA Administrator Mr. Scott Pruitt was somehow involved in the December 2016 decision to remove Dr. Peter Infante from EPA's Science Advisory Panel to review glyphosate. Mr. Chairman, Dr. Infante was removed during the SAP during President--from the SAP during President Obama's term while Gina McCarthy was the Administrator. And since Greg Pruitt was sworn in February 17, 2017, there really is no rational basis to justify this claim. So I hope the minority will be able to explain that statement.

I yield, Mr. Chairman.

Chairman SMITH. Thank you, Mr. Weber.

Ms. JOHNSON. Mr. Chairman?

Chairman SMITH. And the gentlewoman from Texas is recognized.

Ms. JOHNSON. I did not request unanimous consent. I simply said I will be attaching the report to my statement.

Chairman SMITH. I think Mr. Weber's point was that it contained something that was not accurate and not factual and we hope you'll take a look at that.

Ms. JOHNSON. I hope everyone will take a look at it.

Chairman SMITH. Okay. Well, Mr. Weber went into some detail as to what was inaccurate, and we'll look forward to your response later on. Thank you, Ms. Johnson. Thank you, Mr. Weber.

The gentleman from Oklahoma, the Vice Chairman of the Committee, Mr. Lucas, is recognized for an opening statement.

Mr. LUCAS. Thank you, Chairman Smith, for holding this hearing on the important topic of scientific integrity of the International Agency for Research on Cancer's Monograph Programme. I look forward to hearing from our panel of expert witnesses this morning and want to thank them for their voluntary appearance before this committee.

First recognized by the World Health Organization in 1965, IARC began as a French initiative to find and root out cancer both in France and around the world. In pursuit of this goal, one of IARC's many endeavors was the

identification and classification of known carcinogens. This has come to be known as the Monograph Programme. While the effort at the time represented the best modern understanding of cancer and the environmental causes, the methods of IARC's Monograph Programme have remained largely unchanged over the years, even as our understanding of cancer has evolved.

This has caused IARC to reach conclusions that not only create unnecessary fear in people, but in some cases causes IARC to reach conclusions that are contradictions to the best available science. This is unfortunate in any scientific program but is completely unacceptable in one in which the United States, through the NIH and through NIEHS, provides the majority of the funding. This is even more true when IARC's conclusions are then utilized as the basis of regulations, for instance, in places such as California of products like Roundup that contain glyphosate.

In 2015, the IARC Monograph Programme categorized glyphosate as ''probably carcinogenic to humans.'' As Chairman Smith explained, IARC's glyphosate Monograph contained substantial portions of alterations and deletions, it appears, to aid the Monograph in drawing a particular conclusion.

While the appearance of agenda-driven manipulation is troubling on its own, it's even more so when considering that IARC's final conclusion is not only on the fringe of the

scientific world but is completely and totally by itself. The respected scientific bodies such as the Environmental Protection Agency, the European Food Safety Agency, or IARC's own parent body, the WHO, has repeatedly found there to be no risk posed to humans when glyphosate is used as directed. Yet, the IARC Monograph Program persists, reviewing and labeling over 900 substances as ''possible'' or ''probable'' carcinogens over the last 40-plus years, while the only labeling--only labeling one as noncarcinogenic.

IARC's explanation for all this is that they simply assess hazard and not risk; therefore, the actual probability that these substances cause cancer cannot be gleaned from their Monographs. If left unchallenged, this would excuse IARC's bad behavior and give a de facto blessing to their refusal to bring their scientific methods into the modern age. This kind of shoddy work is unacceptable from any scientific body, let alone one funded by the American taxpayer.

The modern agricultural revolution, of which glyphosate and other IARC-labeled ''carcinogenic'' herbicides have played an enormous role, has helped feed the world and enabled struggling nations to grow and gain a footing on the world stage. All of this, however, is threatened by IARC's flawed scientific analysis. Far too often, farmers, ranchers, and small businesses find themselves on the

receiving end of burdensome regulations like those that stem from IARC's misleading assessments. We should be working to reduce the burdens of these hardworking Americans, not funding the growth of them.

And when a federal or international agency makes decisions that have the potential to directly and negatively impact American citizens, we in Congress have a duty to ask questions to address the concerns of our constituents. Similarly, when a federal or international agency utilizes American tax dollars to reach conclusions that directly contradict the overwhelming majority of scientific knowledge, we have a duty to ask how they came to that conclusion.

This committee has, on several occasions, attempted to gain a greater understanding of IARC's decision-making process. Unfortunately, the Committee's simple request for IARC to provide a witness to testify on the Monograph Programme has been met with resistance. The pursuit of an awesome goal like the eradication of cancer should not, cannot, prevent us from asking questions regarding the processes and methods utilized to reach a certain conclusion. Simply because an organization has a commendable goal should never mean the conclusions it draws are beyond reproach.

I look forward to hearing from our witnesses today not only about the problems in the methods and procedures of the

IARC Monograph Programme, of which there are many, but also about the fixes they believe that can be made to bring the Monograph Programme back into line with modern science.

And with that, Mr. Chairman, I yield back the balance of my time.

[The statement of Mr. Lucas follows:]

********** INSERT 4 **********

Chairman SMITH. Thank you, Mr. Lucas.

And the gentlewoman from Oregon, the Ranking Member of the Environmental Subcommittee, is recognized for her statement.

Ms. BONAMICI. Thank you, Mr. Chairman. I'm glad we're having this hearing today about the chemical review process.

Ranking Member Johnson is correct. For too long industries' influence on this process as endangered the public's health and safety. Today, there is an assault on independent scientists and independent scientific organizations by the Trump Administration particularly by the Environmental Protection Agency. It is important that we review the methods and tactics that industry has used it to influence this Administration and attack independent scientific organizations like the World Health Organization's International Agency for Research on Cancer or IARC.

This hearing today will focus on IARC's hazard assessment of glyphosate, a key ingredient in Monsanto's Roundup broad-spectrum herbicide used to kill weeds and grasses. In 2015, IARC determined that glyphosate was probably carcinogenic to humans. Other reviews, including a draft Human Health Risk Assessment released by the EPA in December, concluded that glyphosate is not likely to be carcinogenic to humans. Part of that discrepancy may be

because these reviews have investigated different issues.

IARC conducts hazard assessments while EPA conducts risk assessments. According to IARC, a cancer hazard is an agent that is capable of causing cancer under some circumstances while a cancer risk is an estimate of the carcinogenic effects expected from exposure to a cancer hazard. Although there seems to be some confusion about these distinct scientific procedures of analysis and the science on this issue still appears unsettled, the attacks by the chemical industry to discredit individual scientists and scientific organizations such as IARC is not.

Internal Monsanto records show that company employees have ghostwritten scientific journal articles on glyphosate, attempted to orchestrate a public outcry over IARC's glyphosate findings, and have targeted specific independent scientists for attack. At a time when most of us are sensitive to the cries of fake news the Monsanto records show in their own words that they have sought to amplify positive messages about glyphosate on social media, neutralize the impact of the IARC decision on glyphosate, and to use industry front groups as a platform for IARC observers and industry spokespersons.

Attempts by industry to mischaracterize the scientific debate appear intended to undercut the scientific evidence regarding the possible dangers of glyphosate and its

potential impact on human health. We must make sure any chemical review is not undone by undue corporate influence or misleading scientific studies.

This is all the more important when the chemicals under review are so widely used. Glyphosate has been used as an herbicide in the United States since 1974, and its use in the United States has grown from 11 million pounds in 1987 to nearly 300 million pounds in 2016. Since its introduction in the United States 1.8 million tons of glyphosate have been applied across the country, and 9.4 million tons of glyphosate has been used on crops around the world. Recent studies have shown that this widescale use of glyphosate has had an impact on our food supplies and communities. Glyphosate has been detected in crackers, cookies, cereals, as well as in organic honey and oatmeal.

Chemical exposures, just like exposures to asbestos or lead or other potentially toxic substances, occur regardless of whether we sit on the left or the right of a particular political issue. The public health implications of these exposures are felt by all Americans and all people. That is exactly why an independent scientific review that is not unfairly or surreptitiously influenced by industry is necessary. We need to come to conclusions regarding the scientific evidence concerning glyphosate's potential impact on human health in a transparent and complete manner.

I look forward to hearing the testimony of our witnesses today, and I'm glad Dr. Jennifer Sass from the Natural Resources Defense Council is here. More than 6 years ago, Dr. Sass wrote a report titled ''The Delay Game: How the Chemical Industry Ducks Regulation of the Most Toxic Substances.'' It's important that the Committee hear her perspective on these issues.

[The statement of Ms. Bonamici follows:]

********** INSERT 5 **********

Ms. BONAMICI. And before I yield back, Mr. Chairman, I have three responses from Dr. Christopher Wild, the Director of IARC, responding to inquiries you made late last year. In summary, Dr. Wild provides factually supported rebuttals to criticisms you and others have made about the IARC glyphosate Monograph, and I ask that these documents be made part of the record.

Chairman SMITH. Without objection.

[The information follows:]

********** COMMITTEE INSERT **********

Ms. BONAMICI. And I yield back the balance of my time. Thank you, Mr. Chairman.

Chairman SMITH. Thank you, Ms. Bonamici. And I'll introduce our witnesses now. Our first witness today is Dr. Anna Lowit, Senior Science Advisor in the Office of Pesticide Programs at the Environmental Protection Agency. Dr. Lowit has been a toxicologist in OPP's Health Effects Division since 1998. During this time, she has provided expert technical advice and guidance on issues related to toxicity, testing human risk assessment, and science policy issues. She was elected co-Chair of the Interagency Coordinating Committee on the Validation of Alternative Methods, a committee of representatives from 16 federal agencies that require, generate, or disseminate toxicological and safety testing information. In January, she was named the recipient of the Society of Toxicology's 2018 Enhancement of Animal Welfare Award. Dr. Lowit received her master's of science and Ph.D. in environmental toxicology from the University of Tennessee.

Our next witness is Dr. Timothy Pastoor, CEO of Pastoor Science Communications. In addition, he is President of the Health and Environmental Science Institute, a D.C.-based nonprofit organization. With over 30 years of international experience, Dr. Pastoor has been involved with fundamental toxicity testing, mode-of-action research, and Human Health

Risk Assessment. For the majority of his career, he led toxicology and risk assessment experts in the conduct of safety, health, and environmental studies to assess risk to humans and the environment. He retired in 2015 and founded the company Pastoor Science Communications, LLC, centered around his passion for advancing sound science. Dr. Pastoor received a Ph.D. in toxicology from the University of Michigan.

Our third witness is Dr. Jennifer Sass, Senior Scientist at the Natural Resources Defense Council. She is also a professorial lecturer in the Environmental and Occupational Health Department at George Washington University. In her work with the NRDC, Dr. Sass brings a highly specialized expertise in U.S. chemicals policy. She has published peer-reviewed journals on the regulation of toxic chemicals and emerging contaminants such as nanomaterials. Dr. Sass earned a master's degree and a Ph.D. in anatomy and cell biology from the University of Saskatchewan Canada and has done postdoctoral work in toxicology at the University of Maryland.

Our final witness today is Dr. Robert Tarone, a Biostatistics Director at the International Epidemiology Institute for 14 years before retiring in 2016. Previously, he was a mathematical statistician at the U.S. National Cancer Institute and a professor in the Department of

Medicine at Vanderbilt University. During his career, Dr. Tarone has provided statistical assistance to a wide variety of laboratory and clinical researchers, including investigators in the field of immunology, DNA repair, and cancer-prone inherited diseases. He received his bachelor of science, master's of arts, and Ph.D. all in mathematics from the University of California Davis.

We recognize and appreciate and welcome you all. And, Dr. Lowit, if you will begin.

STATEMENTS OF ANNA LOWIT, SENIOR SCIENCE ADVISOR, OFFICE OF PESTICIDE PROGRAMS, ENVIRONMENTAL PROTECTION AGENCY; TIMOTHY PASTOOR, CEO, PASTOOR SCIENCE COMMUNICATIONS; JENNIFER SASS, SENIOR SCIENTIST, NATURAL RESOURCES DEFENSE COUNCIL; AND ROBERT TARONE, MATHEMATICAL STATISTICIAN, U.S. NATIONAL CANCER INSTITUTE, AND BIOSTATISTICS DIRECTOR, INTERNATIONAL EPIDEMIOLOGY INSTITUTE

STATEMENT OF ANNA LOWIT

Ms. LOWIT. Good morning, Chairman Smith, Ranking Member Johnson, and the rest of the members of the committee. My name is Anna Lowit. I serve as a Science Advisor for EPA's Office of Pesticide Programs. I have a Ph.D. in environmental toxicology and have worked in the area of pesticide risk assessment and toxicology for nearly 20 years.

EPA regulates the manufacture and use of all pesticides in the United States and establishes maximum levels for pesticide residues in food, safeguarding the Nation's food supply, workers, and the general public.

In addition to evaluating new pesticides before they can enter the market, EPA reevaluates existing pesticides at least every 15 years under a program known as registration review. EPA must complete registration review for more than

700 pesticides by October 1 of 2020. In 2017, EPA evaluated more than 120 pesticides using the risk assessment process.

Glyphosate, commonly known as Roundup, was initially registered by EPA in 1974. Glyphosate is one of the most widely used herbicide in the United States with about 270 million pounds of active ingredient applied annually. Glyphosate is used on a large number of crops, primarily corn and soybean, and is commonly used by homeowners.

Registration review for glyphosate was initiated in 2009 using the statutory registration review process applied to all registered pesticides. As part of this process, several types of assessments have been initiated, including evaluations of human health, ecological risk, carcinogenicity, endocrine disruption, and risk to pollinators. The assessments are subject to extensive technical review and public comment throughout the review process.

EPA released the draft Human Health and Ecological Risk Assessments in December of 2017. Glyphosate is considered to have little to no hazard when exposures to the skin or when inhaled. Effects in laboratory animals were only seen through ingestion at very high doses. In the case of glyphosate, the Human Health Risk Assessment was developed with conservative exposure assumptions. Even with these conservative assumptions, no risk to humans, including

infants and children, were identified. This conclusion showing no risk to humans is consistent with risk assessment findings in other countries and by international organizations such as Canada and the European Food Safety Authority.

Glyphosate was also subject to endocrine screening. Based on weight-of-evidence considerations, there's no convincing evidence of potential interaction with estrogen, androgen, or thyroid pathways, and no additional endocrine related studies are considered necessary.

In 2016, EPA conducted a comprehensive analysis of all the available laboratory animal carcinogenicity, mutagenicity, and epidemiology data to inform the human risk--the human cancer-causing potential of glyphosate. EPA presented its evaluation to the FIFRA Scientific Advisory Panel and received the panel's recommendation in March of 2017. The Agency's cancer issue paper was updated to incorporate revisions, and based on the comprehensive analysis of all available data and reviews, EPA concluded that glyphosate is not likely to be carcinogenic to humans.

While the draft Human Health and Ecological Risk Assessments are already publicly available on EPA's website, the official public comment period for the draft risk assessments and supporting science evaluations will soon be announced in the Federal Register. EPA will evaluate the

public comments and, if needed, will revise the risk assessments and then issue a proposed interim decision for public comment. If necessary, the proposed interim decision may include labeling changes and other risk mitigation measures. After public comments on the proposed interim decision are received and evaluated, EPA will issue an interim decision. EPA plans to complete a final decision after an endangered species assessment is complete.

Thank you for the opportunity to testify today, and I'm looking forward to questions from you and the members.

[The statement of Ms. Lowit follows:]

********** INSERT A **********

Chairman SMITH. Thank you, Dr. Lowit.

And Dr. Pastoor?

STATEMENT OF TIMOTHY PASTOOR

Mr. PASTOOR. Chairman Smith--good morning, Mr. Chairman, Ranking Member Johnson, and the distinguished members of this committee. Thank you for inviting me to this important hearing on a very important subject.

I am representing myself and nine other co-authors of a paper that we wrote. These are individuals that are--that come from the private sector and the public sector, professors that come from both the United States and the European area, as well as retired senior scientists from the United States EPA.

My testimony today is going to focus on the scientific process that IARC uses, which the nine authors that I co-authored the paper with have concluded is badly outmoded and in need--in bad need of significant revision or termination. The reason is because the program uses an antiquated and irrelevant hazard classification scheme to simply declare a substance to be carcinogenic or not and provides no context about when, why, or how that substance might actually cause that effect.

Let me illustrate it this way. I would imagine that

most of the people in this room have consumed water or food or both that contained a substance that IARC Monographs Programme has declared to be carcinogenic. How does that make you feel? Well, the problem with that is that it's a simple declaration about something that is in your food that could cause cancer. What I'm talking about is caffeic acid. Caffeic acid is found in a number of foods that we eat every day that are part of a healthy diet, including things like grapes, apples, blueberries, lemons, oranges, and it goes on. And oh, by the way, caffeic acid is also part of the cup of coffee that I have in front of me today. Declaring that caffeic acid is a carcinogenic substance is really of no help when you just state it that way. It needs to have context.

As a toxicologist, I'm frequently asked by family and friends what it means when they hear something is declared to be possibly or potentially carcinogenic. What they want to know is how likely is that to happen to me, my family, my friends. It's an important subject. My answer is always the same. It depends on how potent the chemical is, the substance is, and how much exposure is required to cause that effect.

Let's take potency first. Unfortunately, the IARC Monograph Programme fails to provide the crucial context of potency and instead lumps highly potent substances like plutonium, sulfur mustard, and neutron radiation in the same

cancer classification as processed meat and salted fish. Clearly, there's a difference, but the IARC Monographs Programme fails to account for potency.

My wife is a registered nurse and an integrative healer who likes to use plant-based remedies. When I tell her that aloe vera and ginkgo biloba are classified by IARC as possibly carcinogenic, she rolled her eyes and said--oh, and by the way, they're classified in the same category with fuel, oil, and gasoline, she simply kind of rolled her eyes back and say, ''No, that can't be.''

Such a classification scheme defies common sense, and yet IARC has maintained this hazard classification scheme for well over--in nearly half-a-century. Along with neglecting the important feature of potency, IARC Monographs Programme also fails to account for potential exposure. Why is that important? Because the central tenet of toxicology is the dose makes the poison. And the best way of giving you a good analogy of that is aspirin. A little bit of aspirin is not going to do anything. A couple tablets of aspirin will relieve your headache, and a bottle of aspirin can kill you. But where IARC stops is labeling something as being able to kill you. What good is that information without the context of benefits and dose?

Nearly all 21st-century regulatory processes such as Dr. Lowit described just previously account for potency and

exposure in their evaluation and therefore the likelihood that an adverse effect like cancer could occur. It's known as risk assessment. However, the IARC Monograph Programme is not risk-based and instead is stuck in a hazard classification scheme created a half-a-century ago with no consideration of potency or exposure.

In addition to being out of step with 21st-century science, the IARC Monograph Programme has also lost credibility because of serious flaws in process. I'm here to talk about the science, not the process, but that is a concerning issue.

Outdated science and flawed process are not without consequence. Telling you that IARC has pegged caffeic acid as a carcinogenic substance in your food and coffee does nothing other than sow fear and uncertainty, which is unhelpful and irrelevant at best and irresponsible at worst. The IARC Monograph Programme needs to be either significantly reformed or abolished.

Thank you very much, Mr. Chairman.

[The statement of Mr. Pastoor follows:]

********** INSERT B **********

Chairman SMITH. Thank you, Dr. Pastoor.

And Dr. Sass?

STATEMENT OF JENNIFER SASS

Ms. SASS. Thank you very much for the opportunity to speak to--before this committee today about this very important topic of scientific integrity, the IARC Monographs, and the important evaluation of glyphosate. I very much appreciate coming before you today.

I've been employed for 17 years at NRDC, the Natural Resources Defense Council, and I have advanced degrees in anatomy and cell biology with specific expertise in environmental health, developmental biology, neurobiology, and molecular biology and am also familiar with the Pesticide Office operations that Dr. Anna Lowit is Science Advisor before because on many, many occasions I've testified either with written or oral comments are both to the Pesticide Office following their review of pesticides and registration, including glyphosate. In addition, I've represented NRDC for over a decade on stakeholder advisory panels to the Pesticide Office so have participated as a public and stakeholder member in those processes.

I also have knowledge of the IARC practices, having been invited to a meeting, a week-long meeting to look at arsenic

and water disinfection byproducts by the Chair at the time the Chief of the Monograph Programme Dr. Jerry Rice, who is a colleague of Dr. Tarone's. There have been two Chairs since then, and the current Chair, Dr. Kurt Straif, was also working at the Monograph Programme during that time, so he brings with his leadership continuity to that program and to IARC's commitment to environmental public health and scientific excellence.

IARC has undertaken over 1,000 substances for evaluation, including important ones like asbestos, tobacco smoke, secondhand smoke, diesel exhaust, formaldehyde, vinyl chloride and arsenic, methylene chloride benzene, and many others. There--many of these--not all of them, but many of them also come with people--stakeholders that have deep economic interests in these substances, and although there have been many, the Director Dr. Christopher Wild of IARC right now stated that the pressure that IARC has received in response to listing glyphosate as a probable human carcinogen group 2A has resulted in unprecedented coordinated efforts to undermine the evaluation, the program, and the organization.

These efforts are largely sponsored and coordinated by the agrochemical industry that sought to support its own regulation--its registration and approval of glyphosate in the United States and around the world, to defend itself in

litigation against farmers that were once Monsanto customers and are now cancer patients, and to prevent the labeling of glyphosate-containing products as a carcinogen in the State of California, which would inform the public.

Dr. Jonathan Samet called these strategies that could be traced to the playbook of the tobacco industry to discredit findings related to active and passive smoking. And I would characterize them the same way.

This hearing is part of a kickoff that happened a few months after the IARC Monographs were made public where an article in The Hill was published asking for exactly this, for the stripping of funding for the IARC Programme by Dr. Bruce Chassy, who failed to acknowledge that he was funded by Monsanto.

As far as the science goes, IARC did not ignore relevant studies. They included all the relevant studies, including the Agriculture Health Study and other review articles that they looked at that were sponsored by many--many were sponsored by Monsanto or the agrochemical industry, as well as published articles. But the key with IARC is that they need to be publicly available. It doesn't necessarily have to be published but publicly available. How else can they verify the findings?

In contrast, EPA's 2017 assessment did rely on some of these review articles that--where the underlying studies were

not made public. And I know the Dr. Tarone is going to talk about some of those. I would ask Dr. Tarone how long it took him to evaluate the underlying data and studies in those because the Greim, et al., for example, was only provided 30 days before the IARC meeting, so there's no way it could have been properly evaluated based on a review article.

The IARC has been following systematic methods that are improved worldwide, and in conclusion, I would like to say that, fundamentally, this hearing is about the ability of a public health agency to call a carcinogen a carcinogen even if that carcinogen makes a huge amount of money for powerful corporations.

Thank you.

[The statement of Ms. Sass follows:]

********** INSERT C **********

Chairman SMITH. Thank you, Dr. Sass.

And Dr. Tarone.

STATEMENT OF ROBERT TARONE

Mr. TARONE. Good morning. My European Journal of Cancer Prevention paper differs from most of the published criticisms that you may have seen in the press and elsewhere of the IARC glyphosate classification. My paper critiques the deliberations of the working group completely on IARC's terms.

I accept that IARC is evaluating hazard rather than risk, but the IARC criteria for determining hazard are reasonable and that the body of studies relied upon by IARC is sufficiently complete to provide a valid assessment of glyphosate. My critique concludes that the IARC classification of glyphosate as a probable carcinogen resulted from a flawed and incomplete evaluation of the very rodent cancer studies that they relied upon.

Although the working group concluded that there was sufficient evidence that glyphosate was an animal carcinogen, I conclude that a proper summary of the rodent studies would have difficulty supporting even the conclusion that there is limited evidence that glyphosate is an animal carcinogen. And I just want to discuss briefly one of several examples in

which exculpatory rodent data were excluded by IARC.

IARC concluded that glyphosate caused cancer in animals primarily on the basis of two studies in CD- mice. In the first study, groups of 50 male and female mice were fed diets with--containing increasing dose levels of glyphosate for 2 years. The original study report noted a positive trend in renal adenomas in male mice. The tumor counts were 0013 at increasing dose levels, and this corresponds to a P value of .019 based on an exact test for dose-response.

Additional pathological examination of renal tumors in this study revealed one new adenoma in an unexposed mouse, and three of the original renal tumors were upgraded from adenomas to carcinomas. So for the final tumor counts after pathology review, they were 0012 for carcinomas, P value of .063, and 1013 for carcinomas and adenomas combined, P equals .065.

Now, these marginally significant findings were considered to be particularly consequential by the IARC working group because of the alleged extreme rarity of such tumors in CD-1 mice, and it was concluded from this study and the study alone that glyphosate caused renal tumors in male mice.

Now, there was no a priori expectation that glyphosate should cause kidney tumors, and ordinarily such a small increase in tumors would not be considered especially

noteworthy since around 20 organs and tissues are typically evaluated in each rodent study. Nonetheless, even that small observed increase would be of concern if there was also evidence of an increase in renal tumors for female mice in that same study. Thus, I was surprised to see that the female data were not reported with a remarkable sentence stating, quote, ''No data on tumors of the kidney were provided for female mice.''

IARC has been evaluating rodent studies for over 40 years and is aware that the renal tumor rates for female mice would've been provided in the same report that provided the male tumor rates. IARC's staff should've been highly motivated to acquire these tumor rates. I obtained the female tumor rates for my review of glyphosate rodent studies in the journal Critical Reviews in Toxicology. This is the Greim, et al., paper that Dr. Sass referred to.

For females, no renal tumors were observed, so there was no evidence of an increase in kidney tumors for female mice exposed to the same high levels of glyphosate as males. But even though there was no evidence that glyphosate caused renal tumors in female mice in this study, the working group still might have argued for a sex-specific effect if there was evidence of such an effect in the second CD-1 mouse study they relied upon. But inexplicably, in spite of devoting three--and I apologize for the--there's an error in the

printed comments; it's three not two paragraphs to the discussion of renal tumors observed in the first mouse study, there is no mention at all of kidney pathology in the one paragraph devoted to the second mouse study, which is simply astounding. IARC staff should've been highly motivated to acquire the renal tumor rates from the second study because of the male results in the first study.

The renal tumor rates for the second study were also provided in a review paper. For males, the renal tumor counts at increasing glyphosate exposure level were two, two, zero, and zero, and this is P equals .042, but for an inverse association, decreasing tumor rates with increasing exposure level. And it's also noteworthy that two of these supposedly extremely rare renal tumors were observed in the unexposed mice in this study. Taken together, these two studies provide no evidence whatsoever to support the conclusion that glyphosate causes renal tumors in male mice, contrary to the working group conclusion. And for completeness no tumors were observed for female mice in the second study.

In conclusion, my published paper notes other instances in which rodent tumor rates that supported the conclusion that glyphosate caused tumors were included in IARC deliberations while tumor rates from those same studies that did not support that conclusion were excluded. The systematic exclusion of exculpatory evidence is inexcusable,

particularly when it's practiced by an influential source such as the IARC Monograph Programme. My paper was published online in August of 2016, and not one of the specific claims of data exclusion in that paper has been refuted. And reports since my paper was published and depositions of key working group members related to lawsuits filed against Monsanto have fully substantiated the facts presented and questions raised my paper.

[The statement of Mr. Tarone follows:]

********** INSERT D **********

Chairman SMITH. Thank you, Dr. Tarone.

Dr. Lowit, in your testimony you mentioned that when mice were injected with large doses of glyphosate that some did manifest symptoms of cancer-like conditions but that when the mice were just exposed to glyphosate, there was no effect. There were no symptoms. It seems to me that that's a huge difference. No one is suggesting that humans be injected with large doses of glyphosate. Why is it that IARC doesn't acknowledge the distinction between high doses that are being injected and simple exposure or inhalation, which has not resulted in any cancer-like symptoms? And it seems to me that they are intentionally misleading the American people, and maybe they have some kind of a vendetta against chemical companies, but why or how do you explain the lack of honesty and openness and transparency by IARC?

Ms. LOWIT. So thank you, Chairman Smith, for that question. So I'm sorry if my South Carolina accent comes out. So it's ingest, so I--through the oral route, not inject through the--

Chairman SMITH. Okay. Ingest--

Ms. LOWIT. Ingest through the oral route.

Chairman SMITH. Okay.

Ms. LOWIT. So I apologize for that lack of clarity.

Chairman SMITH. But my--

Ms. LOWIT. So the question is--so I think it's

important that--I'm not going to comment on the value of the IARC process. I can tell you that EPA has been fully transparent in our evaluation. Our draft issue paper was reviewed by the Scientific Advisory Panel. In fact, the transcript from that meeting is publicly accessible. We're now looking forward to public comment on our white paper for the cancer.

Chairman SMITH. Any--was that--I didn't understand that. It's just a statement as to why you think they have been less than transparent?

Ms. LOWIT. I think that's--I'm not going to debate the transparency of IARC.

Chairman SMITH. Okay.

Ms. LOWIT. What we have done at EPA whereas in cases where IARC has looked at review articles, we've acquired the raw study reports, so we've been able to look at information. The full study reports for IARC cannot do that.

Chairman SMITH. I'm just curious. When you talked about large doses of ingestion by the mice, how much are you talking about? A large percentage of their body weight or how much were they--did they ingest?

Ms. LOWIT. So in terms of toxicology studies, often studies--and with glyphosate are in the ingestion of hundreds of milligrams per kilogram per day and what we define as the limit dose. Internationally, most regulatory organizations

recognize 1,000 milligrams per kilogram per day as international standard for the limit dose. And in most--in many cases, glyphosate studies are actually done at that limit dose--

Chairman SMITH. Okay.

Ms. LOWIT. --which is why we conclude there's very little hazard.

Chairman SMITH. And it's very unlikely that any human would ingest anything near to that equivalent amount?

Ms. LOWIT. Oh, no.

Chairman SMITH. Okay. Dr. Pastoor, you pointed out--and I was going to highlight as well--that I think IARC has found that something like 999 out of 1,000 substances created cancer. Only one was deemed to be probably not cancer-causing. Do you think that their process is flawed, their investigations are flawed, and do you think they have predetermined conclusions they're trying to reach?

Mr. PASTOOR. They may or may not. I can't really comment in particular on glyphosate. I'm not here representing a critique or a defense of glyphosate. But what I would say is that there is a flaw in their scientific process. When you don't take into consideration potency--which, Chairman Smith, you just brought up--is that if a significant portion of a body weight of an animal is being overwhelmed with a particular chemical, whether it's

glyphosate or anything else, and you're declaring something to be carcinogenic, that's erroneous science. That's offsetting. That's misinforming the public, and it doesn't serve any process and it's actually more harmful than helpful.

Chairman SMITH. Okay. I agree. And I like that phrase ''erroneous science.'' I'm going to adopt it in this case and maybe in other instances as well.

Dr. Tarone, you wrote a paper in 2016 and you came to the conclusion that IARC's designation of glyphosate was a result of a, quote, ''flawed and incomplete evaluation of experimental evidence.'' What is the general scientific community's response been to that paper? And what was IARC's response?

Mr. TARONE. There's been surprisingly little response actually. I've been amazed.

Chairman SMITH. Okay.

Mr. TARONE. But with regard to IARC, I mean, this paper has gone through an incredible--I mean, it's the weirdest experience I've ever had in 44 years of publishing in peer-reviewed journals. And it's--I mean, I just--really, it's stunning. But IARC did eventually submit a letter to the journal responding to my paper, and I received this in January of 2016. And--no, 2017, I'm sorry, and I responded to their letter. And I assumed that both letters would be

published in the journal along with the paper. IARC's letter was not responsive to any of the specific criticisms I raised.

Chairman SMITH. Okay.

Mr. TARONE. They complained about, you know, ''Who wrote--who paid you to do this and what role did they play in writing and editing the paper?'' They raised technical issues about what constitutes a research study and that this wasn't a research study, but they didn't deal with any of the specifics.

Chairman SMITH. Okay.

Mr. TARONE. And for some reason neither letter was published, and I've never been fully--

Chairman SMITH. Okay.

Mr. TARONE. I don't know. I can't figure out why that happened.

Chairman SMITH. The point being IARC was not responsive to the substance of your--

Mr. TARONE. Not to the substance, and as I said, nobody has specifically refuted any of the claims that I've made about the exclusion--

Chairman SMITH. Okay.

Mr. TARONE. --of rodent studies that should have been included.

Chairman SMITH. Okay. Thank you, Dr. Tarone. That

concludes my time.

And the gentlewoman from Texas, the Ranking Member, Ms. Eddie Bernice Johnson, is recognized for her questions.

Ms. JOHNSON. Thank you very much, Mr. Chairman.

Let me precede my question with this statement. I don't believe any company puts anything on the market that they knowingly know that it harms people. I think it's like the little book Who Moved My Cheese? Sometimes, it's hard to change when you find out what the facts are. And so--and every company that has any respect for itself is going to defend itself when it can.

But I want to ask Dr. Sass. Can you discuss the importance of keeping the development of scientific assessments on chemicals such as glyphosate and other toxic chemicals free from undue influence by industries or others? An example is what are the consequences if chemical risk assessments are driven by industry, and more importantly, if industry-sponsored chemical assessments are given the same weight and authority as truly independent scientific studies?

Ms. SASS. Thank you. I would like to comment on that, and I think that glyphosate is a perfect example of where that's happening because we can really see the difference in when you have an IARC assessment, which is a public health agency of the World Health Organization that links it to some level of carcinogenicity probably carcinogenic in humans.

And then you have--based--including on Monsanto's studies and other studies supported by the registrant, and then you have agencies that are calling it not likely carcinogenic, EPA, which is a regulatory agency.

And I want to talk about some of those differences because the impact on public health is severe potentially. First of all, Mr. Smith's comment about the doses that there--that they were--that--well, what Anna suggested what--that they were at high doses, I want to talk about the limit dose for a quick second because it has a toxicological definition, and these studies did not exceed it. So an arbitrary 1,000 mgs per kg per day was not what IARC used. They used a toxicological definition. And these studies didn't exceed it at the high dose, so they should have been included.

Dr. Pastoor's statement referencing 16th century Paracelsus medicine, to then criticize IARC being half-a-century behind is just ridiculous. Paracelsus did say the dose makes the poison, and there's a lot of truth in that, but that's not the whole truth. The truth is that what's being missed here is considering vulnerable populations potentially. We need to protect the EPA, and regulatory agencies need to be able to protect the whole population, so--including pregnant women and children, elders, people with preexisting diseases and chronic

diseases, people that are high-end users or highly exposed in--as well as the Keith Richards of the world. We need to bracket all of those people and protect them.

And, Dr. Tarone, I do have some answers for the exclusion of those rodent data, but primarily, they weren't available to IARC and IARC relies on public data. The data sets were huge. They were hidden in appendices. The IARC only had it 30 days in advance. But in addition, had IARC had those data, it would have likely come up with an even stronger link to cancer because there was even more tumors than Dr. Greim, the author of that review article, had revealed. Those have all come to light now through EFSA, so the European Food Safety Authority. They've been reanalyzed separately by non-industry scientists. And we now know that there's data that also show tumors in the animals linking to malignant lymphomas and hemangiosarcomas, which, Dr. Tarone, I think you didn't analyze. I think you may have focused on the kidney tumors only.

So, in addition, Dr. Greim, the author of that paper, is not only of questionable scientific integrity for failing to report all those tumors but also ethical potential as well. He's the main author in some diesel emissions studies that put monkeys into chambers being reported in the New York Times right now. So--

Mr. TARONE. Can I respond?

Mr. LUCAS. [Presiding] Dr. Tarone, would that be appropriate for the Ranking Member?

Ms. JOHNSON. Yes.

Mr. LUCAS. It's her time. Please respond.

Mr. TARONE. Well, it's totally incorrect to say that IARC should not have acquired those data because if--and I want to say something about the Greim paper. I relied on the Greim paper only for the data. They included supplemental tables with that review paper that included the underlying basic tables of tumor rates from every study that they reviewed. So I was not relying on Greim, et al., for their conclusion in any sense. I was only relying on it for the data.

Ms. SASS. Well, the summary tables can be used, and EPA had those data for years, probably decades and didn't ask for the underlying data, so to blame IARC for not having gotten it in 30 years--

Mr. LUCAS. The gentlelady's time is expired.

The Chair would note to my colleagues we now have a series of three votes underway that, once the votes are over, we will return and continue this hearing. And with that, the hearing will stand in recess subject to the call of the Chair.

[Recess.]

Mr. LUCAS. This full committee hearing of the Science

Committee is reconvened. I will return to regular order, and I believe I was the next one in line to ask questions, so I'll recognize myself for 5 minutes.

And with that, I turn to Mr. Tarone. Would you care to expand and explain a little bit more about your analysis of the Monograph 112 program and all those issues?

Mr. TARONE. Yes. I specifically want to answer a couple of issues that Dr. Sass raised. First with regard to hemangiosarcomas, I did consider hemangiosarcomas, and it in fact is one of the examples in which IARC excluded exculpatory data. In the second mouse study where they did not discuss renal tumors, they emphasized the finding in hemangiosarcomas that Dr. Sass referred to. And there were four hemangiosarcomas in the highest dose group, and that was all--none in the other three groups.

But in the first mouse study, the one where they spent three paragraphs on renal tumors, they didn't mention hemangiosarcomas, so it's the same thing that happened with renal tumors. So--and it turns out that in that study there was one hemangioma in the low-dose group and one hemangiosarcoma in the mid-dose group and none in the highest-dose group. And by the way, that highest-dose group, glyphosate was 3 percent of the diet that they ate for every day for 2 years. It's an incredibly high dose. So you would have--if what they saw in the second study was a true high

dose effect, you would have expected to see it in the first study. And--but again that was not even mentioned in the IARC Monograph.

And Dr. Sass also raised the issue of the accuracy of the tumor rates that I got from the supplemental tables in the Critical Reviews in Toxicology paper. And in fact, as I pointed out at the end of my comments, everything in my paper has in fact been substantiated by things published since, including comments submitted to the EPA glyphosate SAP by Chris Portier, who was the scientific expert for the IARC working group. And his comments were presenting his statistical analysis of all of the rodent studies that EPA was considering. And they considered many more than IARC, but they also considered all the studies that IARC relied upon.

If you look at his tables upon which his analysis was based, in every case in which I indicated in my paper that IARC had excluded tumor rates, those tumor rates are in those tables in the comments he submitted to EPA. They were included in his EPA analysis, which is an admission that they should have been included in the IARC analysis. Moreover, they were exactly the rates that I reported that I got from the supplementary tables in the Greim, et al., review. So certainly, Christopher Portier now thinks that those rates are okay.

Mr. LUCAS. Thank you, Doctor.

Dr. Pastoor, could you visit with us for a moment about the ways in which the current Monograph Programme classification system on carcinogenicity might be outdated? Expand on that, please.

Mr. PASTOOR. Well, the primary reason that it's outdated and outmoded and needs to either be scrapped or considerably revised is because they stick with a hazard classification system. All they do is declare something as being carcinogenic or not. Modern 21st-century risk-assessment-oriented regulatory programs such as what Dr. Lowit has described with the United States EPA uses that risk-based system to put hazard in context of risk: how much would cause that effect; what is the potency of that particular chemical? IARC was created over--nearly 50 years ago, and they really haven't progressed beyond the point of only classifying things by its carcinogenicity but not putting it in the context of risk.

Mr. LUCAS. Thank you. I think with that now I will yield back and turn to--I think in the next order would be the gentleman Mr. Tonko for 5 minutes for questions.

Mr. TONKO. Thank you, Mr. Chair. And welcome, everyone.

This hearing has been framed around the need to uphold scientific integrity standards in publicly funded research.

If that is a serious concern for this committee, then I implore us to take up H.R. 1358, which I've authored, the Scientific Integrity Act. This Congress has a duty assigned directly to this committee to ensure that public or publicly funded science is conducted, reviewed, communicated to the public and incorporated into policymaking transparently and free from distorting political, ideological, financial, or other undue influence.

Public science informs national policy on everything from pesticides to power grids. Our nation's cities and States need credible information to prepare for climate change. Our families deserve to know if unsafe chemicals are being sprayed on their food, dumped in their water, or added into the products they buy. As representatives, we need to reach conclusions on these high-stakes questions based on rigorous independent scientific facts, not predetermined opinions. We have a duty to ensure that political interference of the scientific process and attacks on the work of federal scientists do not get on the way of our safeguard our public health and our national security.

The rules and norms of our public science are standards that have made America a leading light in the global scientific community for decades. We have seen those standards being actively and deliberately eroded over the past year. Scientists should always be held to the highest

ethical and professional standards. In return, it is our job to uphold standards that ensure scientists are not impugned for reporting their impartial findings.

The Scientific Integrity Act restores our baseline for scientific independence by requiring every federal agency that funds or conducts scientific research to establish clear scientific integrity standards and set basic requirements for how the agency will adhere to those principles.

Science is not about getting the results you want. Scientific integrity is about ensuring a process and atmosphere in which the science leads us to real, unvarnished results. The issue we should be focused on is whether glyphosate is safe, and finding the answer to this question is too important for us to let this be a partisan issue. These are chemicals that people have in their homes. This is on the food our children eat. We should be able to trust that the science we rely upon to make public health decisions is not being distorted or manipulated.

While the tactics used by industry to influence science may have dramatic negative consequences on the independence and credibility of scientific review boards or advisory panels, the real victims of this kind of designed ignorance are everyday people. Without credible science to determine safe levels of exposure, millions of people around our country will be at risk.

Dr. Sass, how do science agencies like a IARC function in order to protect the public health?

Ms. SASS. Thank you. IARC and other public health institutes put out very credible information about the potential hazards of chemicals and other substances. After reviewing all the data, IARC, for the glyphosate assessment, brought experts from all over the world from multiple different countries. They have different areas of expertise. They all come together as a working group. They--all of the discussion of all of the data--publicly available data is done in front of everybody. There's a plenary session where people get to also discuss what the different subject matter experts have come up with in their area.

And the result of these very credible, transparent, publicly generated hazard assessments is to then support potentially risk assessments but also to support nonregulatory or even non-risk-related decisions that can be made, for example, not only by government regulatory agencies but also by forward-thinking companies and businesses looking to work with safer or less toxic or less hazardous chemicals are starting to replace it in their products. There's retailers that care about this. There's a whole area of green chemistry that's very interested in this, and of course medical professionals, occupational health experts, all of these people care about understanding the hazard of materials

even if they don't--haven't--there hasn't been a full risk assessment to understand potency and dose-response and the other things that come afterwards.

Mr. TONKO. And why is it important that independent bodies review chemicals for potential exposure risks?

Ms. SASS. Well, all the available data should be looked at. I believe that, but that's also what the agencies believe and it's what IARC did. Many of the studies that relied on were supported or sponsored by the regulated industry, and that's fine. That's normal. That happens. But there are systematic review procedures for reviewing and evaluating confidence in those studies on a lot of different parameters. And if all of those different parameters aren't available to do a proper robust review and assessment of the confidence, then it's more difficult. And so we should--instead of a priori making decisions about what data is in or out of the pot, it should all be looked at and reviewed, which is what IARC did.

Mr. TONKO. Thank you. Mr. Chair, I have several documents which I would like included in the record, including the Monsanto battle plan, laying out their preliminary attack on IARC, the IARC preamble defining the roles of working group members and participants, a list of participants from the IARC glyphosate Monograph commentaries by several scientists on the strength of the IARC glyphosate

evaluation, the FIFRA Science Advisory Panel report from December 2016 concluding that EPA did not follow its own guidelines for carcinogen risk assessment in evaluating glyphosate, and a letter from the United Nations special rapporteur stressing how essential the work of the National Institute of Environmental Health Science is to protecting human rights.

Mr. LUCAS. Without objection.

[The information follows:]

********** COMMITTEE INSERT **********

Mr. LUCAS. And the gentleman's time is expired.

Mr. TONKO. Thank you, Mr. Chair.

Mr. LUCAS. The Chair now turns to the gentleman from Texas, Mr. Babin, for 5 minutes.

Mr. BABIN. Thank you, Mr. Chairman. I appreciate it. And thank you to the witnesses for being here.

Dr. Anna Lowit, if you don't mind, the EPA's risk assessment process explicitly includes opportunities for experts who did not contribute to the assessment to review and comment on a draft of the scientific analysis, is that correct?

Ms. LOWIT. That's correct.

Mr. BABIN. Okay. The EPA's risk assessments like the one on glyphosate developed by the Office of Pesticide Programs are also subjected to rigorous independent peer review. Is that correct?

Ms. LOWIT. So EPA's cancer evaluation has been subject to the FIFRA Scientific Advisory Panel. That's true.

Mr. BABIN. Okay. As I understand it, the National Academies, which is similar to IARC, develops reports by expert panels and has outside peer reviews and evaluate each and every report to ensure scientific accuracy. However, unlike EPA and NAS, IARC Monographs do not employ any independent outside peer reviews. Instead an IARC Monograph working group collaborates behind closed doors to select

studies, analyze data, and reach conclusions. So without any public engagement or independent scientific peer review, the working group acts hand-in-hand with IARC staff as judges, juries, and executioners. Clearly, these IARC procedures fall well short of meeting 21st-century standards for transparency and scientific credibility. And I would like to know if you agree with that.

Ms. LOWIT. So what I can answer is EPA's transparent approach, that our cancer evaluation was reviewed by the FIFRA--excuse me--Scientific Advisory Panel. The transcript from that meeting is actually publicly available. Our document is now available for public--will be open for public comment. It's been released on our docket, and so our process is quite transparent.

Mr. BABIN. Do any of the other witnesses agree with that statement? Now, let me repeat it. Without any public engagement or independent scientific peer review, the working group acts hand-in-hand with IARC staff as judge, jury, and executioner. IARC procedures fall well short of meeting 21st-century standards of transparency and scientific credibility. Would you other three agree with that? Dr. Pastoor?

Mr. PASTOOR. Yes, I would generally agree with that. I think IARC needs to be brought up to the standards of transparency that is exhibited by the United States EPA.

Mr. BABIN. Okay. Thank you. Dr. Sass?

Ms. SASS. I disagree because the meetings are open at IARC. Observers are invited. Monsanto was present. Other regulatory interests can also be present, so they're public in that sense that anybody who wants to be present can.

And I also want to point out that EPA's Scientific Advisory Panel review of the ''not likely'' classification didn't agree with that classification.

Mr. BABIN. Dr. Tarone?

Mr. TARONE. Yes, I wouldn't agree completely with the statement, but what I believe is that right now the Monograph Programme appears to think they have--they're accountable to no one, so I do need--I do think that they need to be brought in and show some accountability to somebody. The fact that they did what they did with the glyphosate working group, I mean, that should not happen. The exclusion of exculpatory rodent studies many times, there's just absolutely no way that should happen, so I would just like to see more accountability.

Mr. BABIN. Absolutely. Okay. Is it scientifically proper to redo a peer-reviewed study's data analysis with a different statistical analysis than was originally used for the study and then use this reanalysis without first ensuring that it undergoes robust independent peer review? Dr. Lowit?

Ms. LOWIT. So the first half of your question is about reevaluating scientific data, and I would agree with that statement, that that is actually part of an independent evaluation of those data is often to reevaluate the statistics. And EPA has actually in fact redone some of the statistics for the glyphosate cancer evaluation.

Mr. BABIN. Okay.

Ms. LOWIT. The second part of your question is about peer review. Peer review is important, and in the case of the cancer evaluation, we did have our statistics evaluated as part of the Scientific Advisory Panel.

Mr. BABIN. Thank you very much.

And Dr. Tarone, could I ask you that question?

Mr. TARONE. I have no problem with people doing independent different types of statistical analysis, although, you know, it does have to be peer-reviewed because sometimes you can pull tricks, you know, get the result you want. I mean, there's a lot of data dredging, p-hacking it's sometimes called that goes on. So peer review is essential, though, when you're evaluating multiple different types of statistical analyses.

Mr. BABIN. Absolutely. And my time is expired, Mr. Chairman. Thank you.

Mr. LUCAS. The gentleman's time is indeed expired.

The Chair now recognizes the gentleman from California,

Mr. McNerney, for 5 minutes.

Mr. MCNERNEY. Well, thank you, Mr. Chairman, and I thank the witnesses.

Dr. Sass, have you ever heard the term chemical trespass?

Ms. SASS. Yes, I have. It's when you find a chemical in--usually an industrial chemical not naturally occurring in your body that you didn't give permission for it to be there.

Mr. MCNERNEY. So do you think that term applies to our hearing this morning?

Ms. SASS. I do and not just to glyphosate but certainly glyphosate. I mean, my guess is that there's not many people in the United States that are unexposed to glyphosate because of how widespread its use is. It's almost 300 million pounds annually, and every--in agriculture, and every one of those pounds are put out onto our fields, our food supplies, get into our rivers and streams and drinking water, sources of drinking water.

Mr. MCNERNEY. Well, some studies claim that human exposure to glyphosate has increased by 500 percent in 25 years. What kind of risks are associated with this kind of proliferation of exposure?

Ms. SASS. So we don't understand the risks, and that's one of the things that I think that EPA, you know, should be

doing is taking on a proper risk assessment after a proper hazard assessment where they acknowledge that there's a carcinogenic risk and then do a proper slope factor. There's proper mechanisms to do that. But the increase is being shown in people's urine, and we're--so we know that for sure. And that's why I think that there's probably no unexposed population, that we're exposed on a daily or routine basis.

Mr. MCNERNEY. Is it also present in mother's milk?

Ms. SASS. It is. It's widespread and it's--because it's water-soluble, it is present in all those fluids.

Mr. MCNERNEY. So even the youngest members of our society are being highly exposed to this chemical?

Ms. SASS. It is, and that's what brings up this dose poison fallacy, this 16th-century, you know, dose poison thing is that although it is true that, you know, we can't be poisoned if we don't dose ourselves, that's true if we're not exposed, it's also true that there's vulnerable populations. And how each of us react to those are differently--are very different so that a pregnant woman or a reproductive-age man or woman might be much more vulnerable to certain effects, reproductive effects, for example. Or if we're exposed to a carcinogen when we're young while our tissues are developing and growing and taking in--as they take in nutrients taking in those toxic chemicals, that could be a much more damaging time. And then the health impacts can be hardwired into the

system, whereas, for example, if I'm exposed to a dose of lead, I have probably no reaction to the same dose of lead that could cause irreparable permanent harm in a developing child.

Mr. MCNERNEY. Thank you. Some folks are critical of the World Health Organization, and other folks are critical of the EPA's risk assessment. Can you explain how those assessments differ?

Ms. SASS. Sure. I mean, primarily, for some reason the--a lot of the criticism which I think isn't fair is on whether IARC considered some studies that actually weren't available to it at the time. And my only answer is they've got to look at publicly available data. That's a rule they made in advance. Industry knows that in advance. If it wants to get those studies to them in advance, they could have done so. The chemicals are nominated. They have plenty of time to do that if they want to. The--fundamentally, though, some of the ways they're looking at it are, for example, EPA is not looking at the high-dose tumors. The animals have tumors at high doses, but there's no other indication of toxicity to the animals at those doses, so there's no real reason not to consider those tumor effects to be real or valid. Like I say, instead of using an arbitrary number, to actually use toxicological ways of assessing whether those doses should be considered. So that's one

important thing is to consider those doses.

The other thing is to--when you look at it, does there have to be a clear dose-response? EPA is throwing out data if there wasn't an--increasing tumors with increasing doses in every study, for example, and that's not appropriate because many reasons. One is that we don't--we--animals react differently, so you have to use your statistics to do that. EPA has used a certain statistical test. I argue some different statistical tests. The EPA cancer guideline says EPA should use whichever one provides the most health-protective outcome.

Mr. MCNERNEY. Thank you. Mr. Chairman, I have an article published this morning by the POLITICO describing the European Parliament's decision to create a special committee to investigate potential failings in the EU system for reviewing pesticides such as glyphosate. The committee will look at whether the European Commission followed appropriate regulations and avoiding conflict of interest when it decided to renew the license for another 5 years. I would like to introduce this story for the record.

Mr. LUCAS. Without objection.

[The information follows:]

********** COMMITTEE INSERT **********

Mr. MCNERNEY. Thank you. And I yield back.

Mr. LUCAS. The gentleman yields back.

The Chair now turns to the gentleman from Arizona, Mr. Biggs, for 5 minutes.

Mr. BIGGS. Thank you, Mr. Chairman. I appreciate all the witnesses being here today.

And I'll start with Dr. Pastoor. You touched on your testimony, but I'd like you to expand if you would on additional examples besides glyphosate that were perhaps classified in a misleading way by IARC.

Mr. PASTOOR. Well, you know, the--what I was trying to get at in my testimony is that things like caffeic acid, arachidonic, these are chemicals that we find in our diet naturally. And by just simply declaring them to be carcinogenic is not helpful to the American public. They need some context with that. And my criticism of IARC is they don't provide that kind of context.

Mr. BIGGS. And so--still with you, Dr. Pastoor. The--you've described that as a misleading way to classify these potential hazards, and you've advocated for a risk assessment as opposed to hazard assessment. And I thought--and I don't want to misinterpret, but I thought I heard Dr. Sass refer to this kind of dose-level-type thing as being 16th-century--a 16th-century approach. Do you want to rebut that?

Mr. PASTOOR. I definitely do. I think it's absolutely as true as it was in the 16th century. And the best example I can give is the one I gave earlier on aspirin is that the dose makes the poison. It's just as good at a low--in fact, the actual statement by Paracelsus in the 16th century was that the difference between a medicine and a poison is the dose. Aspirin is a good example of that. Two tablets will relieve your headache. A bottle full of it will kill you. That's the dose makes the poison. It's as true today as it was back in the 16th century and long before that.

It's important to realize that because in some of these studies that are being cited here, whether it's glyphosate or otherwise, these are animals that have been packed full of some of these chemicals for a lifetime. And I'm probably one of the few people in this room that's actually conducted those very studies. And they go on for 2 years. They're given to animals at the maximum dose that they can get, and even though Dr. Sass refers to the animals not having any adverse effects, they're getting as much as 3 percent of their diet of that particular chemical. That's outrageous. It's something that no human would ever see, and the results are meaningless and not useful in the context of risk assessment and communication of that information to the American public.

Mr. BIGGS. And, Dr. Lowit, I want to just ask you

quickly--I don't want my time to totally expire here, but the EPA sets tolerance levels for residue of glyphosate, and you've talked about the actual exposure to chemicals, not simply ask if a chemical could ever be a carcinogen. And EPA takes a different approach than IARC. Why does EPA take the approach it takes?

Ms. LOWIT. So EPA is a risk-based organization, which is consistent with federal statute and largely for the reasons that Dr. Pastoor just explained, that it is important to assess not only the hazard but the exposure of a particular chemical. And it is at that intersection of hazard and exposure where we understand risk. And our job is to understand risk to the American people.

Mr. BIGGS. And I'm going to close out here by just covering a couple of statements. We've heard one of--previous questioners--when he was giving his statement prior to asking question says we don't want the, quote, ''science we rely on is not distorted or manipulated,'' close quote. He didn't want that--our science to be distorted or manipulated. And additionally, the idea of independent bodies look at this--we want independent bodies to be looking at these types of chemicals and potential hazards to us.

But what if there is a conflict of interest? And I'm going to introduce--Mr. Chairman, without objection, I'd like to introduce a letter written in 2002, 15 years ago or so, by

one of our panelists Dr. Sass where she noted that IARC's working groups are made behind closed doors, no transcripts of the deliberations are publicly available. Most significant, the voting of the working group members is never made public. This lack of transparency and lack of public oversight makes peer review impossible.

In the letter that we received back from Dr. Wild, at this point there's no indication that any of the processes have changed in the last 16 years, and thus, I'm very concerned about IARC and their processes in this issuing these monologues and--or, excuse me, Monographs. And with that, Mr. Chairman, I introduce that letter.

Mr. LUCAS. Without objection.

[The information follows:]

********** COMMITTEE INSERT **********

Mr. LUCAS. The gentleman yields back the balance of his time?

Mr. BIGGS. I do, thank you.

Mr. LUCAS. And the gentleman--or the Chair now turns to the gentleman from Colorado, Mr. Perlmutter, for 5 minutes.

Mr. PERLMUTTER. Thanks, Mr. Chair.

And, Dr. Sass, I'm just going to ask you a pretty open-ended question. I've been able to sit through some of this testimony. Obviously, there's some very different approaches and opinions just listening to the last 15 minutes. So are there some issues that you think really need to be brought out in more detail? And if so, what are they?

Ms. SASS. Thank you. With regards to the IARC 2002 letter, which I point out is quite a long time ago, at that time that was three Chiefs of the Monograph Programme ago, and at that point we were concerned that they were allowing people with financial conflicted--conflicts of interest to be part of the voting working group. And since then, they have established conflict guidelines that are world-renowned. They're very well-respected, they're very well-implemented, and those kinds of things are well-tracked and well-reported, and so there's a comfort level. And so those issues are not--have not been relevant for a long time.

As far as the differences between the two assessments,

it really is a difference between whether you're doing the hazard only and then going to risk assessment or whether you're conflating them together. And IARC is a hazard only. They just say whether there's an association with cancer or not, and then if you want to do a risk assessment or deregulatory actions, those things will come differently.

I do not understand what EPA is not going through its process to develop a slope factor and a dose response and a potency estimate and instead just doing--calling it not likely, dismissing quite a lot of evidence of tumors.

And you're wrong about Dr. Portier. He's actually updated his tables, and there's quite a few tumors there, which I would be happy to submit or have someone else--have him submit to the record that have been disregarded.

What I don't understand is why the Pesticide Office is working with the EPA's Office of Chemical Safety and Pollution Prevention, which is the science policy office, which is headed by Dr. Nancy Beck, a former chemical industry lobbyist, to implement a systematic review procedure for its data that was reviewed by the National Academies in 2007 and was called fundamentally flawed, something the National Academies have never called anything before, instead of, for example, working with the EPA IRIS program, the Integrated Risk Information System program, which is in the Office of Research and Development, the science office of EPA, and

which could work with them to develop potency estimates and slope factors and then a risk assessment at that point.

Mr. PERLMUTTER. So--let me see. So the real difference here is one is just sort of purely data-driven in determining, you know, whether or not there's potential carcinogens, and then there's kind of a political and, you know, policy decision being made as to, okay, it's risky, it's not, the dose is okay, the dose is not okay, but it's problematic to begin with, but we've looked at it, you know, on behalf of the EPA and the country and say, you know, this is okay, but there's a problem. Is that--am I off?

Ms. SASS. No, you are spot on.

Mr. PERLMUTTER. Okay. Well, then with that, I'm going to yield back.

Mr. LUCAS. Before the gentleman yields back, would he yield to the doctor from the EPA for a comment?

Mr. PERLMUTTER. Sure. Which--yes.

Mr. LUCAS. Dr. Lowit.

Ms. LOWIT. Thank you for that. So I just think it's important that we make sure the record is accurate. The Office of Pesticide Program is actually part of the Office of Chemical Safety and Pollution Prevention. And in fact Dr. Sass' comments about systematic review and the IRIS program are inaccurate. The IRIS program, as publicly discussed in many venues in the last year, is actually moving to a

systematic review with just the recommendations of the National Academies of Sciences. So EPA's evaluation is consistent with the National Academies.

Mr. PERLMUTTER. Dr. Sass, do you have a comment on that?

Ms. SASS. Yes, there's two different systematic reviews happening within EPA and parallel. One is being developed by Dr. Nancy Beck, a former ACC American Chemistry Council lobbyist until very recently, and one is being developed by the scientist within the IRIS program. The IRIS program, it doesn't prioritize or preferentially treat industry-supplied data, whereas the other systematic review does. For example, guideline studies--GLP it's called, good laboratory practices, which were developed for industry studies specifically to stop them from lying and cheating about their data. If you apply systematic review properly, you would look at all the data with the same rules.

Mr. LUCAS. The gentleman's time is expired.

Mr. PERLMUTTER. My time is expired. I yield back to the Chair.

Mr. LUCAS. And on that note, the Chair is going to turn to the gentleman from Louisiana, Mr. Higgins, for 5 minutes.

Mr. HIGGINS. Thank you, Mr. Chairman. I thank the panelists for appearing before us today.

We have certainly challenging issues in front of us regarding what's real and what's not. We all want to protect the American people from unnecessary harm, but we also want to move forward with sound science as we do so. So this is a bipartisan effort, and I'm quite sure that the scientists before us and the experts that have testified before us and have met with us in our offices agree that we have a common goal here, that the American farmer feeds the world.

And the studies that I've read, including EPA reports and various other research documents, use verbiage like ''most likely'' and ''probable'' and ''potentially increased risk'' regarding the primary chemical within Roundup. It's a herbicide used to increase crop yield.

So I clearly recall a few years ago the rumor that plastic bottles cause cancer. It was widespread. Now, we all drink from plastic bottles. I've never seen a colleague eat the bottle.

So the usage of Roundup in reality on farms across America and in households is used very carefully because it's very expensive. They use computerized dispersion on large farm machinery to carefully disperse the stuff. Protective clothing is worn.

So I would say that a hungry child that the American farmer feeds across the world by the compassion and generosity of our nation, Mr. Chairman, a hungry child is

concerned about the--overcoming that hunger at that moment with food provided by the American farmer, as opposed to most likely, probable, or potentially increased risk of cancer sometime down the line.

So I have a question. You said something, Dr. Lowit, very interesting earlier. You stated that EPA conducted its assessment of glyphosate with conservative risk assumption. Can you please clarify for us what that means? What is a conservative risk assumption?

Ms. LOWIT. So as a measure to be resource efficient in our risk assessment process, we use a tiering process when we evaluate exposure. Our tier 1 assessments use high-end estimates that are health protective and often even compound those assumptions together. And in the case of glyphosate we've done a health protective tier 1 level for--in most cases--assessment that uses health protective conservative assumptions and came to the conclusion, despite those conservative assumptions, that there's no risk to humans, including infants and children.

Mr. HIGGINS. Would you recommend changes to the IARC to make this program--in this program to ensure transparency and reliable reporting to the public that you're attempting to inform? Is there some improvement or streamlining of the scientific process where data can be shared amongst perhaps conflicting conclusions by various scientists, including

scientists from other--from organizations from other nations? Can there be more transparency and inclusion of scientific data so that we can come to a conclusion? Because, you know, the loss of Roundup would definitely hurt the production of crop yield across the world, and there'd be an immediate impact felt worldwide. So do you have suggestions on how to improve the process so we can arrive at the truth ultimately?

Ms. LOWIT. So EPA is not bound by our IARC conclusions, as noted in my testimony. We've come to the conclusion that glyphosate is not likely carcinogenic to humans, and that's similar to many other nations in the world, including our Canadian colleagues and the European Food Safety--

Mr. HIGGINS. European colleagues. I concur.

Dr. Sass, could you add to that?

Ms. SASS. Well, the European assessment is being investigated because it's been shown that they took the first draft from Monsanto and they barely redlined it. So I don't think that should be held up as the high bar.

And as far as transparency and the use of glyphosate, I just think a proper risk assessment should be done. And what's happening here is that the EPA is doing the hazard assessment calling it not likely without doing the slope factor and the risk assessment I'm guessing because it favor Monsanto's interest for selling it abroad.

Mr. HIGGINS. Do you recommend that Roundup be pulled from the market?

Ms. SASS. No, that has not been our recommendation.

Mr. HIGGINS. Thank you. Mr. Chairman, I yield back.

Mr. LUCAS. The gentleman yields back.

The Chair now recognizes my neighbor from the great State of Kansas, Dr. Marshall, for 5 minutes.

Mr. MARSHALL. Well, thank you, Chairman. And I guess I would start by--you had a standing joke with my pastor, and every week he would ask me, ''Does coffee cause cancer this week, Doc?'' And I would say, ''Well, I hope not'' because I usually had a cup of coffee in my hands. So I just continue to be amazed. I'm reading this and I see that IARC, once upon a time, actually said it was a carcinogen, so that shocks me.

I'm also a little bit surprised to see that the United States has given $48 million to IARC, which is located in Lyon, France, a beautiful place by accounts of all the paintings I've seen of that area, but I'm not sure why we're spending American dollars over there.

You know, to go to my question, I'll start with Dr. Pastoor, the first one. Obviously, there's a big difference between hazard and risk, and on its webpage, IARC contends that it does not make a judgment about risk. So IARC says it does not make a judgment about risk. However, on the front

page of its Monograph, it states that it evaluates carcinogenic risk to humans. This seems really misleading. I'm a biochemist. I'm a physician. You can go down the dirt here a little bit if you want to, but if it's not saying--talking about making judgment regarding to risk, saying something is carcinogenic is exactly declaring it's a risk. Can you help me understand this better?

Mr. PASTOOR. Representative Marshall, thank you for that question because that's core to the testimony that I'm giving today, and that's that the difference between the word hazard and risk is absolutely crucially important because if a patient comes to you and says, ''Well, what should I do about caffeic acid?'' or caffeine or whatever they're asking you about, you have to put that in context, minimize your exposure or avoid it altogether, whatever it is.

What IARC does is stops with half a loaf, half of the description. They're just saying it's carcinogenic and leaves it at that point. It is not a risk assessment. It's simply a hazard assessment. That's not useful. It's actually injurious. It's also I think irresponsible, and I think it's harmful to the American public.

Mr. MARSHALL. And one of our jobs here in Congress is to prioritize the dollars we do have on research. And in Kansas we have big issues with the sugarcane aphid, with the wheat mosaic virus. I mean, to me, prioritizing monies for

those would seem to be--take precedent over this.

I'll go to Dr. Lowit with my next question. I think just to hammer this point home, explain to me the EPA--so I'm new to Congress. How does the EPA make its assessment? Is it hazards only? When you determine what chemicals are safe or not, do you use just the hazard assessment or how do you do it?

Ms. LOWIT. So, consistent with federal statute, EPA does risk assessments, so we evaluate both the hazard and the exposure and then evaluate them together.

Mr. MARSHALL. Does that often lead to a--are there examples of some chemicals that are a hazard only and--as opposed to a risk as well?

Ms. LOWIT. As a general rule, no. EPA does risk assessment, not hazard assessment.

Mr. MARSHALL. Okay. Thank you. I yield back.

Mr. LUCAS. The gentleman yields back. I believe everyone's had an opportunity for questions.

Does the Ranking Member have any concluding comments?

Ms. JOHNSON. I don't. Thank you.

Mr. LUCAS. The Ranking Member does not.

The Chair simply wishes to thank our panel for being here and to express our appreciation for the insights gained today. Obviously, this is a subject matter that we will continue to delve into with great depth.

And in particular to our fellow public official from the EPA, I appreciate the challenges you're caught between.

With that, the record will remain open for 2 weeks for additional written comments and written questions from the members.

This hearing is adjourned.

[Whereupon, at 12:32 p.m., the Committee was adjourned.]

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